DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 7/6/2009 have been fully considered but they are not persuasive. Regarding claims 1, 3, 5-7, 10, 13 and 36, applicant argues that the lead of Lampadius is not adapted for rupturing in response to applied force produced when the lead is pressed against a treatment site. However, this functional language can clearly be accomplished by the lead of Lampadius. Specifically, if a tremendous amount of force where applied against the ampul when it was pressed against a treatment site, it would eventually rupture due to the force. As such, the lead is clearly "adapted" to perform that functional language. Alternatively, if the lead were pressed against the tissue while an applied force was simultaneously applied by the sharp tip, the functional language would still be met, as the capsule would "rupture in response to applied force produced [by a physician] when said lead is pressed against a treatment site." The lead of Lampadius is clearly capable of performing the functional language included in the claim since it includes all of the structural limitations of claim 1.

2. Regarding claims 18, 20, 23, 24, 27, 30-32 and 35, the applicant argues that the radial edge/guard 81 cannot be advanced through the lumen of catheter 79. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Claim 18 merely

requires that the lead be capable of being advanced through the catheter. As seen in figure 3 of Lampadius, the catheter and lead are not connected, and as such, the lead can be moved forward and backward in the catheter. Furthermore, the guard 81 prevents the glue segment from contacting a wall of the catheter lumen, since the guard prevents the glue segment from entering the catheter lumen.

3. The rejections of claims 1, 3-7, 10, 11, 13, 18, 20, 21, 23, 24, 26-28 and 30-36 are still considered proper.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 3, 5-7, 10 and 13 rejected under 35 U.S.C. 102(b) as being anticipated by Lampadius (DE 2453840).

6. Regarding claims 1, 10 and 13, Lampadius discloses a medical lead as shown in figures 1-3. The figures all show the distal end of the lead body 23, which includes a glue segment 67 disposed around a tip electrode 65. The glue segment comprises a tissue adhesive encapsulated in a biocompatible capsule (i.e., "plastic ampul") that is formulated to rupture when said lead is urged against a treatment site, liberating the tissue adhesive, and affixing the lead body to the treatment site (see the second to last paragraph in the translation). Specifically, the glue segment is adapted for rupturing in response to applied force produced when the lead is pressed against a treatment site.

This functional language can clearly be accomplished by the lead of Lampadius. Specifically, if a tremendous amount of force where applied against the ampul when it was pressed against a treatment site, it would eventually rupture due to the force. As such, the lead is clearly "adapted" to perform that functional language. Alternatively, if the lead were pressed against the tissue while an applied force was simultaneously applied by the sharp tip, the functional language would still be met, as the capsule would "rupture in response to applied force produced [by a physician] when said lead is pressed against a treatment site." The lead of Lampadius is clearly capable of performing the functional language included in the claim since it includes all of the structural limitations of claim 1.

7. Regarding claim 3, Lampadius discloses the adhesive may be a 2-butyl cyanoacrylate (i.e., "Butyl-2-zyanoakrylat").

8. Regarding claim 5, the distal end 81 is considered a guard for the glue segment, since it extends out past the glue segment, much like the guard 18 shown in figure 1 of the applicant's specification.

9. Regarding claims 6 and 7, Lampadius discloses the glue segment is torus-shaped, which is both annular and tubular.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lampadius in view of Munch et al. (US 6,463,335, hereinafter Munch). While Lampadius discloses the applicant's basic invention, including a tissue adhesive for securing a medical lead to the heart, Lampadius is silent as to using a fibrin glue as the tissue adhesive. Attention is directed to the secondary reference of Munch, which discloses a electrode secured to the heart by using a fibrin glue (Col. 20, lines 1-32). Therefore, it would have been obvious to one of ordinary skill in the art to substitute fibrin glue for the n-butyl cyanoacrylate of Lampadius since both are known

biocompatible tissue adhesives, and both would work equally well in securing a lead to the heart.

14. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lampadius in view of Williams et al. (US 6,516,230, hereinafter Williams). While Lampadius discloses the applicant's basic invention, including a tip electrode for contacting the heart, Lampadius is silent as to using a tip electrode shaped as a helix coil. Attention is directed to the secondary reference of Williams, which discloses a tip electrode 16 in the shape of a helix coil (Col. 3, lines 5-6). Therefore, it would have been obvious to one of ordinary skill in the art to substitute the helix electrode of Williams for the tip electrode of Lampadius since both are known tip electrode configurations, and the helix electrode has the benefit of providing additional anchoring at the treatment site.

15. Claims 18, 20, 23, 24, 27, 30-32 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lampadius in view of Starksen.

16. Regarding claims 18, 27, 30 and 32, Lampadius discloses a medical lead as shown in figures 1-3. The figures all show the distal end of the lead body 23, which includes a glue segment 67 disposed around a tip electrode 65. The glue segment comprises a tissue adhesive encapsulated in a biocompatible capsule (i.e., "plastic ampul") that is formulated to rupture when said lead is urged against a treatment site, liberating the tissue adhesive, and affixing the lead body to the treatment site (see the second to last paragraph in the translation). Furthermore, the distal end 81 is considered a guard for the glue segment, since it extends out past the sides of the glue

segment, much like the guard 18 shown in figure 1 of the applicant's specification, and also extends out past the distal end of the lead body, and would prevent the glue segment from contacting a wall of a catheter lumen as the lead is advanced therethrough.

17. However, while Lampadius does disclose the use of a catheter 23,79 for insertion of the lead, Lampadius is silent as to advancing the lead through the catheter for insertion at the proper site. Attention is directed to the secondary reference of Starksen, which discloses a guide catheter 10 with a lumen wide enough to accommodate cardiac leads (Col. 4, lines 5-12). After placing the catheter in the proper location, and utilizing balloon 18 to protect the heart tissue (Col. 4, lines 29-40), the lead will be advanced through the catheter to a treatment site (Col. 5, lines 58-65). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to modify Lampadius to utilize a catheter as described in Starksen, since this is a known apparatus for the introduction of leads in the heart and would have allowed an electrical lead to be properly implanted at a treatment site.

18. Regarding claim 20, Lampadius discloses the adhesive may be a 2-butyl cyanoacrylate (i.e., "Butyl-2-zyanoakrylat").

19. Regarding claims 23 and 24, Lampadius discloses the glue segment is torus-shaped, which is both annular and tubular.

20. Regarding claims 26 and 31, Lampadius discloses that the adhesive could be delivered through a lumen in the lead and forced through ports 17 (see figure 1). As the adhesive is forced through the ports, two dots will inherently form.

21. Regarding claim 35, an implantable medical device must inherently be connected to the lead in order to apply the electrical energy.

22. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lampadius and Starksen in view of Munch et al. (US 6,463,335, hereinafter Munch). While Lampadius discloses the applicant's basic invention, including a tissue adhesive for securing a medical lead to the heart, Lampadius is silent as to using a fibrin glue as the tissue adhesive. Attention is directed to the secondary reference of Munch, which discloses a electrode secured to the heart by using a fibrin glue (Col. 20, lines 1-32). Therefore, it would have been obvious to one of ordinary skill in the art to substitute fibrin glue for the n-butyl cyanoacrylate of Lampadius since both are known biocompatible tissue adhesives, and both would work equally well in securing a lead to the heart.

23. Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lampadius and Starksen in view of Williams et al. (US 6,516,230, hereinafter Williams). While Lampadius discloses the applicant's basic invention, including a tip electrode for contacting the heart, Lampadius is silent as to using a tip electrode shaped as a helix coil. Attention is directed to the secondary reference of Williams, which discloses a tip electrode 16 in the shape of a helix coil (Col. 3, lines 5-6). Therefore, it would have been obvious to one of ordinary skill in the art to substitute the helix electrode of Williams for the tip electrode of Lampadius since both are known tip electrode configurations, and the helix electrode has the benefit of providing additional anchoring at the treatment site.

24. Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lampadius and Starksen in view of Sigg et al. (US 6,931,286, hereinafter Sigg). Lampadius, as modified above, discloses the applicant's basic inventive concept with the exception of the catheter including mapping electrodes. Column 5, lines 20-30 of Sigg describes the use of a mapping catheter during the implantation of electrical leads. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention from the teaching of Sigg et al. to modify the system of Lampadius by adding a lumen in the lead in order to apply the tissue adhesive to the application site and to also include mapping electrodes in order to locate a desirable application site.

25. Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lampadius and Starksen in view of Igo et al (US 6,666,844, hereinafter Igo). Lampadius, as modified above, disclose the applicant's basic inventive concept with the exception of the catheter having a suction capacity. Column 6, line 65 of Igo discloses a passage 120 in the catheter that is to supply a vacuum to withdraw fluid. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention from the teaching of Igo to modify the system of Lampdius, as modified, by adapting the catheter to apply suction to a tissue site in order to remove excess moisture from the site.

26. Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lampadius in view of Williams et al. (US 6,516,230, hereinafter Williams).

27. Lampadius discloses a medical lead as shown in figures 1-3. The figures all show the distal end of the lead body 23, which includes a glue segment 67 disposed around a tip electrode 65. The glue segment comprises a tissue adhesive encapsulated in a biocompatible capsule (i.e., "plastic ampul") that is formulated to rupture when said lead is urged against a treatment site, liberating the tissue adhesive, and affixing the lead body to the treatment site (see the second to last paragraph in the translation). Furthermore, the distal end 81 is considered a guard for the glue segment, since it extends out past the sides of the glue segment, much like the guard 18 shown in figure 1 of the applicant's specification, and also extends out past the distal end of the lead body, and would prevent the glue segment from contacting a wall of a catheter lumen as the lead is advanced therethrough.

28. While Lampadius discloses the applicant's basic invention, including a tip electrode for contacting the heart, Lampadius is silent as to using a tip electrode shaped as a helix coil. Attention is directed to the secondary reference of Williams, which discloses a tip electrode 16 in the shape of a helix coil (Col. 3, lines 5-6). Therefore, it would have been obvious to one of ordinary skill in the art to substitute the helix electrode of Williams for the tip electrode of Lampadius since both are known tip electrode configurations, and the helix electrode has the benefit of providing additional anchoring at the treatment site.

Allowable Subject Matter

29. Claim 12 is allowed.

30. The following is an examiner's statement of reasons for allowance: a medical lead with a glue segment, encapsulated within a biocompatible capsule, extending outward from a distal end surface of a lead body in a direction that is substantially aligned with the longitudinal axis of the elongated lead body while also being disposed within a tip electrode, when combined with the rest of the limitations of the claim, has not been taught or suggested by the prior art..

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

31. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric D. Bertram whose telephone number is (571)272-3446. The examiner can normally be reached on Monday-Thursday from 9-5 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl H. Layno can be reached on 571-272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/E. D. B./
Examiner, Art Unit 3766

/Mark W Bockelman/
Primary Examiner, Art Unit 3766
October 29, 2009